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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,585	02/08/2002	Marek Kwiatkowski	11989-008001	2835
26191 7590 01/18/2007 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/071,585	Applicant(s) KWIATKOWSKI, MAREK	
	Examiner Frank W Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,10-13,18,20-23,29,32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,17,19,24,26-28,34 and 35 is/are rejected.
- 7) ☒ Claim(s) 3,6-9,14-16 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on June 1, 2006 has been entered. The claims pending in this application are claims 1-29 and 32-35 wherein claims 4, 5, 10-13, 18, 20-23, 29, 32, and 33 have been withdrawn due to species election. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on June 1, 2006.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-28, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 27 is rejected as vague and indefinite. Since step a) of the claim does not require that non-bifunctional oligonucleotides lacks said first separation tag or lacks said second separation tag, it is unclear how to elute the non-bifunctional oligonucleotides lacking said first separation tag as recited in step c) of the claim and how to elute the non-bifunctional oligonucleotides lacking said second separation tag as recited in step e) of the claim. Please clarify.

5. Claim 26 is rejected as vague and indefinite. Since step d) of the claim requires only cleaving either said first separation tag or said second separation tag, it is unclear how to elute an

Art Unit: 1634

oligonucleotide lacking said first separation tag and an oligonucleotide lacking said second separation tag in the same time as recited in step e) of the claim. Please clarify.

Response to Arguments

In page 7, second paragraph bridging to page 8, second paragraph of applicant's remarks, applicant argues "[S]tep (e) does not recite eluting two separate oligonucleotides, one lacking the first separation tag and one lacking the second separation tag. Rather, the oligonucleotide eluted in step (e) lacks both separation tags. The eluted non-bifunctional oligonucleotides originally had one separation tag, and were adhered to the separation medium as recited in step b) of amended claim 1. Cleavage of the separation tag in step d) of claim 26 results in a non-bifunctional oligonucleotide that lacks both of the separation tags and thus it can be eluted from the column in step e) of claim 26".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because claims 1 and 26 do not require that non-bifunctional oligonucleotides have one separation tag and claim 26 does not limit that an oligonucleotide lacking said first separation tag and an oligonucleotide lacking said second separation tag are from a non-bifunctional oligonucleotide as argued by applicant.

6. Claim 34 recites the limitation "the oligonucleotide" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no word "oligonucleotide" in the step f). Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 14, 17, 19, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonora *et al.*, (Nucleic Acids Research, 18, 3155-3159, 1990).

Regarding claims 1 and 7, Bonora *et al.*, teach providing a plurality of oligonucleotides, said plurality of oligonucleotides (ie., crude synthesized oligonucleotides) comprising at least one bifunctional oligonucleotide (ie., synthesized oligonucleotides with desired length) and at least one non-bifunctional oligonucleotide (ie., synthesized short truncated oligonucleotides) wherein each said at least one bifunctional oligonucleotide comprises a first separation tag (ie., phosphate group at the 5' end or hydroxyl group at the 3' end) attached to a first end of said at least one bifunctional oligonucleotide and a second separation tag (ie., phosphate group at the 5' end or hydroxyl group at the 3' end) attached to a second end of said at least one bifunctional oligonucleotide, and wherein cleavage of said first or said second separation tags yields an oligonucleotide having a 3' hydroxyl moiety, contacting said plurality of oligonucleotides with a separation medium (ie., DEAE column or reverse HPLC column) under conditions effective for adhering said at least one bifunctional oligonucleotide and at least one non-bifunctional oligonucleotide to said separation medium, and selectively eluting at least one non-bifunctional oligonucleotide (ie., synthesized short truncated oligonucleotides) as recited in claim 1 wherein said first and said second separation tags are different (ie., phosphate group at the 5' end and

Art Unit: 1634

hydroxyl group at the 3' end) as recited in claim 7 (see page 3157, left column pages 3158 and 3159, and Figure 3).

Regarding claim 2, Bonora *et al.*, teach that said non-bifunctional oligonucleotides comprise truncated oligonucleotides (ie., synthesized short truncated oligonucleotides) (see Figure 4 in page 3158).

Regarding claim 14, Bonora *et al.*, teach that a cleavable unit of either of said first or said second separation tags is selected from the group consisting of acid labile, fluoride ion labile, photolabile, redox labile (ie., hydroxyl group at the 3' end), and electrophilic labile moieties.

Regarding claims 17 and 19, Bonora *et al.*, teach that said separation medium is ion exchange separation media (ie., DEAE column) as recited in claim 17 and said separation medium is a reversed phase separation medium as recited in claim 19 (ie., reversed phase HPLC column) (see page 3157, left column and Figure 4 in page 3158).

Regarding claim 24, Bonora *et al.*, teach further comprises eluting said at least one bifunctional oligonucleotide (ie., synthesized oligonucleotides with desired length) (see Figure 3 in page 3158).

Therefore, Bonora *et al.*, teach all limitations recited in claims 1, 2, 7, 14, 17, 19, and 24.

9. Claims 1, 7-9, 14, 17, 19, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Blocker *et al.*, (US Patent No.4,997,927, published on March 5,1991).

Regarding claims 1 and 7, Blocker *et al.*, teach providing a plurality of oligonucleotides, said plurality of oligonucleotides (ie., crude synthesized oligonucleotides) comprising at least one bifunctional oligonucleotide (ie., synthesized oligonucleotides without a

Art Unit: 1634

trityl group) and at least one non-bifunctional oligonucleotide (ie., synthesized oligonucleotides with a trityl group at the 5' end) wherein each said at least one bifunctional oligonucleotide comprises a first separation tag (ie., trityl group at the 5' end or hydroxyl group at the 3' end) attached to a first end of said at least one bifunctional oligonucleotide and a second separation tag (ie., trityl group at the 5' end or hydroxyl group at the 3' end) attached to a second end of said at least one bifunctional oligonucleotide, and wherein cleavage of said first or said second separation tags yields an oligonucleotide having a 3' hydroxyl moiety, contacting said plurality of oligonucleotides with a separation medium (ie., DEAE column) under conditions effective for adhering said at least one bifunctional oligonucleotide and at least one non-bifunctional oligonucleotide to said separation medium, and selectively eluting at least one non-bifunctional oligonucleotide (ie., synthesized oligonucleotides with trityl group) as recited in claim 1 wherein said first and said second separation tags are different as recited in claim 7 (see column 2, lines 29-65 and Figure 1).

Regarding claims 8 and 9, Blocker *et al.*, teach that either of said first or said second separation tags comprise a separation unit selected from the group consisting of alkoxytrityl, alkoxypixyl, alkylthioformacetal, methylthioalkyl, derivatives of mercaptodimethoxytrityl or mercaptotrityl, and a hydrocarbon chain introduced in a form era linear or branched diol, and combinations thereof as recited in claim 8 wherein said alkoxytrityl is selected from the group consisting of decyloxymethoxy trityl (C10Tr), 4-hyloxymethoxytrityl (C6Tr), dimethoxytrityl (DMTr), and monomethoxytrityl (MMTr) as recited in claim 9 (see column 4, lines 47-67).

Regarding claim 14, Blocker *et al.*, teach that a cleavable unit of either of said first or said second separation tags is selected from the group consisting of acid labile (ie., trityl that can

Art Unit: 1634

cleaved by acid), fluoride ion labile, photolabile, redox labile, and electrophilic labile moieties (see column 2, lines 52-67).

Regarding claim 17, Blocker *et al.*, teach that said separation medium is ion exchange separation media (ie., DEAE column) as recited in claim 17 (see column 2, lines 43-51).

Regarding claim 24, Blocker *et al.*, teach further comprises eluting said at least one bifunctional oligonucleotide (ie., synthesized oligonucleotides without a trityl group) (see column 2, lines 29-65 and Figure 1).

Therefore, Blocker *et al.*, teach all limitations recited in claims 1, 7-9, 14, 17, and 24.

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

August 21, 2006

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

FRANK LU
PRIMARY EXAMINER